

ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826

Remarks

Claims 1-22 are pending. Claims 1-4, 9-10, and 15-22 are withdrawn. Claims 5-8 and 11-14 are under consideration. Claims 5, 11, 13 and 14 are amended herein for clarity. Claims 6 and 12 are amended to more particularly point out the invention. Support can be found in the specification on page 6, line 8. New claims 23-26 are added to more distinctly claim the invention. Support for these amendments and new claims can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments and new claims add no new matter. In light of these amendments and new claims and the following remarks, applicants respectfully request entry of these amendments and new claims, reconsideration of this application, and allowance of the claims.

35 U.S.C. § 112, second paragraph

Claims 5-8 and 11-14 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The Office alleges that claim 5 is vague because the claim recites a method for detecting conception in an animal, the body of the claim fails to recite a complete method of detection. The Office states that the claim only recites a step for detecting the presence of early conception factor in a body fluid of the animal. The Office goes on to state that there is no step for contacting the body fluid with the appropriate reagents for detection of the early pregnancy

ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826

factor and no correlation step that relates the detection of early pregnancy factor to conception in the animal which is the purpose of the method recited in the preamble.

Claim 5 is amended herein by adding a contacting step and reciting a correlation to more distinctly define the invention. Support can be found in the specification on page 7, lines 19-21. Applicants believe that this rejection is overcome and respectfully request that it be withdrawn and that amended claim 5 be allowed.

B. The Office alleges that claim 11 is vague because the recitation of “the antibody-early conception factor complexes” lacks antecedent support.

Claim 11 is amended herein by deleting the phrase “the antibody-early conception factor complexes” and substituting therefor “binding of the antibody to early conception factor, wherein the binding indicates the presence of early conception factor in the animal.” Applicants believe that this rejection is overcome and respectfully request that it be withdrawn and that amended claim 11 be allowed.

C. The Office alleges that claim 13 is vague because the recitation of “the receptacle” lacks antecedent support. The Office goes on to state that claim 13 is also vague because it recites the use of a substrate or inducer but lacks an enzyme (or other reagent as the “detectable moiety”) to react with the substrate or inducer to generate a “detectable change” that is monitored. The Office also states that if the “detectable moiety” is an enzyme, claim 13 is incomplete since it lacks a separation that removes unbound “detectable moiety.” The Office goes on to state that the lack of such a separation step would produce a positive result whether the early conception factor is present or not in the sample.

**ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826**

Claim 13 is amended herein by deleting the term “the receptacle.” Further, amended claim 13 now recites a washing step, thereby removing the basis for this rejection. Support can be found in the specification on page 6, lines 15-16. Applicants believe that these rejections are overcome and respectfully request that it be withdrawn and that amended claim 13 be allowed.

D. The Office alleges that claim 14 is incomplete because it lacks a separation step to remove unbound alkaline phosphatase, horseradish peroxidase, or urease if these enzymes are conjugated to the antibodies. The lack of such a separation step would produce a positive result whether the early conception factor is present or not in the sample.

Amended claim 13 recites a washing step, thereby rendering moot the rejection of claim 14, which depends on amended claim 13. Therefore, applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 102

A. Claims 5, 6, 11, 12, and 13 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Morton et al. Specifically, the Office Action states that “Morton et al. (WO 86/05498) discloses various immunoassay methods for detecting pregnancy in animals by detecting the presence of early pregnancy factor (i.e. early conception factor) in serum.” The Office goes on to state that the “various immunoassay methods utilize antibodies on solid phases alone or in combination with enzyme labeled antibodies to detect the early pregnancy factor/early conception factor (see pages 6-8).”

For a prior art reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in that single reference. Further, the disclosure in that

ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826

single reference must be enabling. If one element of the claimed invention is not disclosed in the prior art reference, there is no anticipation. It is settled law that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently.” Verdegaal v. Union Oil, 814 F2d. 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987).

The Office’s rejection of claims 5, 6, 11, 12, and 13 is based on an erroneous presumption. Specifically, the Office errs when it presumes that early conception factor is the same protein as the early pregnancy factor described by Morton et al. The instant application discloses purified Early Conception Factor, a glycoprotein, having a molecular weight between 190,000 and 205,000 daltons. See in the specification page 5, lines 7-10. Morton et al. does not disclose the molecular weight of early pregnancy factor. Nevertheless, the Office alleges, without any scientific basis, that early pregnancy factor is the same as Early Conception Factor and thus the claimed invention is not novel. Specifically, the Office Action incorrectly uses the phrases “early pregnancy factor (i.e. early conception factor)” and “early pregnancy factor/early conception factor” to imply that early pregnancy factor and early conception factor are the same protein. See Office Action, page 4, paragraph 4, lines 4-5 and lines 6-7.

M.P.E.P. § 2131.01 states that “[n]ormally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to: (A) prove the primary reference contains an ‘enabled disclosure;’ (B) explain the meaning of a term used in the primary reference; or (C) show that a characteristic not disclosed in the reference is inherent.” The Office has failed to show that the early pregnancy factor described in Morton et al. (WO

86/05498) is the same protein as the Early Conception Factor of the instant application.

Moreover, the Office has cited no extrinsic evidence to show that the early pregnancy factor described by Morton et al. (WO 86/05498) is the same protein as the Early Conception Factor of the present application.

In contrast, applicants provide herewith references (extrinsic evidence) from the art that characterize early pregnancy factor and show that it is not the Early Conception Factor of the claimed invention.

In a reference attached as Exhibit A, "Early pregnancy factor: its role in mammalian reproduction-research review," *Pregnancy and Sterility*, 35(4), 397-402, 1981, Smart et al. discloses that early pregnancy factor has two activity peaks of 180,000 and 40,000 molecular weight, respectively. (See page 398, column 2, paragraph 2.) In another reference attached as Exhibit B, "Production *in vitro* of mouse early pregnancy factor and purification to homogeneity," *J. Reprod. Fert.* 71:581-592, 1984, Cavanagh, a co-inventor of WO 86/05498, characterizes early pregnancy factor as having an elution profile comprising several peaks. Cavanagh teaches that a 500,000 MW form and a 240,000 MW form of early pregnancy factor are associated with carrier proteins. See page 587, paragraph 1. Further, this reference discloses that an elution fraction, identified as fraction 21, contained the activity of early pregnancy factor and was found to have a molecular weight of approximately 21,000. See page 591, line 2. Each of these references shows that the protein referred to in the art as early pregnancy factor does not have a molecular weight between 190kD and 205kD, which is a defining characteristic of Early Conception Factor.

ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826

Because Morton et al. (WO 86/05498) does not disclose the molecular weight of early pregnancy factor, the extrinsic evidence provided by applicant establishes that the molecular weight of early pregnancy factor is different from the molecular weight of Early Conception Factor of the claimed invention. Thus, the early pregnancy factor of the prior art, e.g., Morton et al., is not the same protein as Early Conception Factor. Because Morton et al. does not disclose Early Conception Factor or any use of it, the claimed invention is not anticipated. Therefore, applicants respectfully request that this rejection be withdrawn and that claims 5, 6, 11, 12, and 13 be allowed.

B. Claims 5-8 and 11-14 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jordan et al. Specifically, the Office states that Jordan et al. (WO 99/39208) discloses various immunoassay methods for the detection of early conception factor in serum, urine, or milk samples from animals. The Office goes on to state that the methods utilize antibodies specific for the early conception factor labeled with enzymes, such as horseradish peroxidase or alkaline phosphatase, or colloidal gold (see pages 5-7).

Jordan et al. (WO 99/39208) is not prior art because its effective filing date (February 2, 1998) is the same as the effective filing date of the present invention. In a Preliminary Amendment, filed May 16, 2001, a copy of which is attached herewith as Exhibit C, applicants amended the instant specification to claim priority to U.S. Serial No. 09/016,995, to which WO 99/39208 also claims priority. Because the instant application and WO 99/39208 have the same

**ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826**

filings date, there is no basis for this rejection. Therefore, applicants request withdrawal of this rejection.

New claims 23-26

New claims 23-26 correspond to claims 5 and 11, respectively, and recite the molecular weight of Early Conception Factor, a novel protein. Support can be found in the specification on page 5, lines 7-10. The prior art does not disclose any protein having the characteristics, e.g., molecular weight, of Early Conception Factor, and, therefore, does not disclose Early Conception Factor or its use. Therefore, applicants believe that these claims are patentable and respectfully request their entry and allowance.

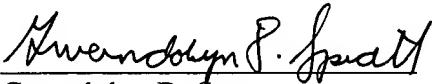
ATTORNEY DOCKET NO. 03073.0001U2
Application No. 09/764,826

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application are believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$55.00 (representing a one-month extension of time fee, small entity) is enclosed herewith. No additional fees are believed to be due; however, the Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

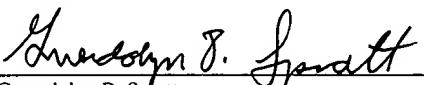
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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Gwendolyn D. Spratt

9-19-03
Date